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The challenges of surgical research in children

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It is generally agreed that advances in surgical care are accelerated by high quality research, and in particular randomized clinical trials. BJS is seldom sent papers reporting controlled trials in children, perhaps reflecting the particular difficulties of conducting research in this age group. These include the ethics of research in children, and issues with the consent process.

It is suggested that the interests of individual children should be balanced with the necessity to conduct research on specific children to benefit children more generally; thus research in children need not be personally beneficial or in the child's best interests. Parents / carers have legitimate authority to make non-harmful decisions about their child in line with their own values, but that children have a right to be respected in their own right. These two obligations are balanced by seeking consensus with children and their parents about the child's involvement in research, i.e. neither the parent nor child strongly opposes involvement.

In the UK, The Clinical Trials Regulations (Medicines for Human Use (Clinical Trial) Regulations 2004 (amended in 2006) define a child (minor) as someone under the age of 16 years. The regulations specify that for a minor to participate in a clinical trial, a person with parental responsibility must give informed consent. For parents who want only the best for their child, it must be difficult to hear that a clinician has equipoise about two different intervention options. Informed consent may be tricky when trying to explain these concepts to both parent and child, but it is good practice to gain the child's agreement to take part in the clinical trial, where possible, regardless of age.

This month's edition of BJS features four articles of topical interest to paediatric surgeons and the allied surgical speciality communities. They cover four major themes in paediatric surgery research. First, and perhaps most obvious, children and adults are different. Diederen and colleagues from the Netherlands highlight outcome metrics for paediatric and adult patients undergoing restorative ileoanal pouch surgery. [1] It was thought that outcomes of restorative surgery were worse in children, but in fact this large Dutch study suggests late failure and pouch outcome are similar in children and adults. The paediatric cohort had more anastomotic pouch strictures, suggesting that focussing on surgical technique specific to children, such as hand sewn anastomosis, rather than stapling, could optimize their outcomes. Other suggestions include paediatric and adult colorectal surgeons working in partnership, and in high volume centres, particularly for rare conditions such as inflammatory bowel disease in children. This structure also facilitates transitional care, when children pass from paediatric to adult surgeons, robustly co-ordinated by gastroenterologists ,

surgeons , nursing staff / stoma therapists and psychologists in multidisciplinary clinics. [2]

Technical papers are also rare in paediatric practice. Gastrostomy is a valuable adjunct in the nutritional management of adult and paediatric patients, traditionally placed using endoscopic assistance. Percutaneous endoscopic gastrostomy (PEG) was pioneered by Dr Michael Gauderer a paediatric surgeon working at the Rainbow Babies and Children's Hospital Cleveland Ohio, USA in the 1980's.[3, 4] In the second paper this month, surgeons and radiologists working at Great Ormond Street Hospital London, UK compared PEG with radiologically inserted gastrostomy in a randomized clinical trial. [5] Both techniques were similarly effective, with low complication rates when outcomes were examined critically. Thus decisions about which technique to use, with appropriately trained staff (surgeon or radiologist), may depend more on resource availability, mindful that the occasional complication (pneumoperitoneum, inadvertent colon puncture, gastrocolic fistula, abdominal sepsis) would require paediatric surgical expertise.

Hand injuries are common in childhood, particularly traumatic nail bed injury when, for example, a finger is trapped in a door. Hand surgeons have long debated the merits, or otherwise, of retaining the injured nail plate to protect the underlying nail matrix. Greig et al report early clinical outcomes of a feasibility study to compare these alternatives (NINJA trial). [6] This pilot randomized study has shown that a definitive trial is possible, and has led to modifications in design that should encourage research funders.

The final paediatric paper this month does not involve clinical outcomes, but equally important communication issues. Young patients coming to hospital for surgical operations experience anxiety and stress which may affect pyschological well being in the short medium and long term. Parents are likewise affected, and experience enormous distress when their child is admitted to hospital. Ryu and colleagues from Korea have employed the virtual reality cartoon character Pororo the Penguin as an interactive intelligence tool to chaperone the young patient through their hospital journey. [7] The positive findings from this study, showing significant reduction in distress, reinforce the actions of a number of institutions worldwide including Alder Hey Children's Hospital Liverpool, UK to employ intelligence tools to help the child and their family through a hospital admission. No doubt there is much more to come in the future with the use of artificial intelligence tools in modern healthcare.

Clinical trials are much needed in children and like many other surgical disciplines, paediatric surgeons are only just beginning to improve the evidence base. [8, 9, 10] Cancer trials in young patients have been the leading example, where national and international partnerships, together with active clinical networks can drive progress and advances in treatment. For example, in the UK the British Association of Paediatric Surgeons aided by Royal College of Surgeons of England are actively engaged in ambitious strategies to promote research leadership roles to support, design and progress trial outputs. Reporting trials in high quality surgical journals like BJS enables wide dissemination of information to the benefit of paediatric surgical practice.

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